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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/790,291 | 03/01/2004 | G. Barrie Kitto | CLFR:232US | 9495 |

7590 02/16/2007
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| EXAMINER |
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WORLEY, CATHY KINGDON

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| ART UNIT | PAPER NUMBER |
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1638

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/790,291

Applicant(s)

KITTO ET AL.

Examiner

Cathy K. Worley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 Decembert 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/4/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

2. The objection to claim 2 is withdrawn in light of the Applicant's cancellation of the claim.
3. The objection to the specification for the use of trademarks is withdrawn in light of the Applicant's amendments to the specification.
4. The rejection of claim 5 under 35 USC 112, second paragraph, is withdrawn in light of the Applicant's amendments to the claims.
5. The rejections of claims 1-5 under 35 USC 112, first paragraph, are withdrawn in light of the Applicant's amendments to the claims.
6. The rejection of claims 1 and 6 under 35 USC 102(b) over Bleil et al. is withdrawn in light of the Applicant's amendments to the claims.
7. The rejection of claims 1-2 and 6 under 35 USC 102(a) over Kirk et al. is withdrawn because the Applicant has correctly pointed out that their priority date precedes this publication.

8. The rejection of claims 1-6 for double patenting over Application No. 10/664,118 is withdrawn in light of the express abandonment of Application No. 10/664,118.

Claim Rejections - 35 USC § 102

9. Claims 1 and 6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kirk et al. (Pre-Grant Publication: US 2004/0175440 A1, published on Sept. 9, 2004; application No. 10/683,611, filed on Oct. 10, 2003 with priority to PCT/US02/11693 which was filed on April 12, 2002), for the reasons of record stated in the previous Office Action mailed on May 26, 2006. The Applicant's amendments received in the response filed on Dec. 4, 2006 have been fully considered but did not render claims 1 and 6 free of the art.

Claims 1 and 6 are drawn to a genetically modified plant that expresses a lactate dehydrogenase-C4 or an antigenic fragment thereof.

Kirk et al. teach transgenic plants expressing the immunocontraceptive lactate dehydrogenase (see page 37, claim 40), and they teach rice plants, wheat plants, and corn plants (see page 37, claim 48). Kirk et al. teach LDHC4 (see page 14, paragraph 0200).

The Applicant argues that teaching LDH is a genus that does not anticipate the species of LDH-C4 (see page 4 of the response received on Dec. 4, 2006). This is

not persuasive, however, because Kirk et al. specifically list LDHC4 (see page 14, paragraph 0200).

The Applicant further argues that the inventor, Dr. Kitto, was in possession of the invention prior to the earliest priority date of Kirk et al. (see last paragraph on page 4 of the response). This is not persuasive, however, because the notebook pages provided in the Declaration do not specify what protein is being quantified. There is no mention of LDHC4 on any of the notebook pages.

Claim Rejections - 35 USC § 103

10. Claims 1-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bleil et al. (WO 98/00440, published on Jan. 8, 1998) in view of Goldberg et al. (Adv Exp Med Biol. (1986) Vol. 207, pp. 395-406), for the reasons of record stated in the previous Office Action mailed on May 26, 2006. The Applicant's amendments and arguments received in the response filed on Aug. 30, 2006 have been fully considered but were not found to be persuasive.

The Applicant argues that the Action has not provided motivation to combine Bleil with Goldberg (see paragraph bridging page 12 of the response). This is not persuasive, however, because the motivation to combine the transgenic plants taught by Bleil et al. with the mouse LDH-C or antigenic fragments thereof taught by Goldberg et al. comes from Goldberg's teaching that LDH-C is a very effective immunocontraceptive (see abstract and page 396 second paragraph).

The Applicant also argues that the Action has not presented motivation to combine Bleil with any protein fragment (see third paragraph on page 12 of the response). This is not persuasive, however, because Goldberg teaches antigenic fragments (see page 402, figure 3 and page 8 of the previous Office Action).

Goldberg specifically teaches fragments consisting of amino acids 211-220 and 231-243 of LDH-C (see page 402, figure 3). Goldberg specifies that these fragments are antigenic, and therefore one of ordinary skill would be motivated to utilize these fragments in an immunocontraceptive, such as that taught by Bleil et al.

The Applicant further argues that the presently amended claims require a LDH-C4 protein, and the rejections in the Action are regarding LDH-C (see fourth paragraph on page 12 of the response). This is not persuasive, however, because the LDH-C taught by Goldberg et al. is also referred to as LDH-C4 and the amino acid sequence is the same as the murine LDH-C4 in the instant claims (see paragraph bridging pages 401-402 where it is referred to as LDH-C4; and see page 402, figure 3 for the amino acid sequence).

11. Claims 1 and 3-6 remain rejected.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW

Nov. 12, 2006



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER